

Finding Reference	1970716-202010-N3	Certificate Reference	MD 78787
Certificate Standard	ISO 13485:2016 & EN ISO 13485	Clause	7.4.3
Category	Minor		
Area/process:	Customer related processes 7.2		
Statement of non-conformance:	The verification of purchased products is not fully effective as the sampling size of incoming goods wasn't seen to have been clearly defined. The organization explained that due to Covid19 pandemic they needed to handle a wide amount of incoming goods and a sampling method was used however no deviation was seen to have been documented in this regard.		
Clause requirements	<p>Verification of purchased product</p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product.</p> <p>When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device.</p> <p>When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information.</p> <p>Records of the verification shall be maintained (see 4.2.5).</p>		
Objective Evidence	Incoming Sensors Testing VM3.COP/37.00 issue 3 of 30/4/2015 PVM 1291 of 27/4/2020		
Cause			
Correction/containment			
Corrective action			